

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 15, 1998 list were made in July, 1998

### New Approvals

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#### ANADA Number: 200-202

Pioneer Product: 140-439  
Trade Name: Phoenectin™ Liquid for Horses  
Ingredients: Ivermectin  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: 06/05/98  
Status: Prescription only  
Route: Oral  
Species: Equine  
Drug Form: Liquid (solution)  
Concentration: 10 mg/mL  
Indications: For the treatment and control of large strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*Strongylus vulgaris*), (adult and migrating tissue stages) (*Strongylus edentatus*) (adult) (*Triodontophorus* spp.); small strongyles (adult and fourth stage larvae) (*Cyathostomum* spp. *Cylicocycylus* spp., *Cylicodontophorus* spp. *Cylicostephanus* spp.); pinworms (adult and fourth stage larvae) (*Oxyuris equi*); ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*); hairworms (adult) (*Trichostongylus axei*); large mouth stomach worms (adult) (*Habronema muscae*); stomach bots (oral and gastric stages) (*Gastrophilus* spp.); lungworms (adults and fourth stage larvae) (*Dictyocaulus arnfieldi*); intestinal threadworms (adults) (*Strongyloides westeri*); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third stage larvae; and dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

21CFR 520.1195

#### ANADA Number: 200-246

Pioneer Product: 091-739  
Trade Name: Anthelban V  
Ingredients: Pyrantel pamoate  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: 06/18/98  
Status: Over-the-counter  
Route: Oral  
Species: Equine  
Drug Form: Liquid (suspension)  
Concentration: 50 mg/mL pyrantel base as pyrantel pamoate  
Indications: For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles in horses and ponies.

21CFR 520.2043

#### NADA Number: 141-100

Trade Name: DECCOX®, BMD®, 3-NITRO®  
Ingredients: Decoquinat, bacitracin methylene disalicylate, roxarsone  
Sponsor: Alpha Pharma, Inc.  
Approval Date: 06/02/98  
Status: Over-the-counter  
Route: Oral  
Species: Avian (broiler chickens)  
Drug Form: Type A medicated articles to make Type C medicated feed  
Concentration: Decoquinat 27.2g/lb (6%); bacitracin methylenedisalicylate 10, 25, 30, 40, 50, 60, or 75 g/lb; roxarsone 45.4, 90, or 227g/lb

## Actions Taken byFDA Center for Veterinary Medicine

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### NADANumber: 141-100, con't

Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. mivati*, *E. acervulina*, *E. maxima*, and *E. brunetti*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens.

Tolerance: 21CFR 556.170: Decoquinate: 2ppm in tissues other than skeletal muscle and 1 ppm in skeletal muscle  
21CFR 556.70: Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of chickens  
21CFR 556.60: Arsenic residues (from roxarsone): 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of chickens.

Withdrawal: 5 days

This NADA provides for the combined use of three approved Type A medicated articles in the manufacture of Type C medicated feeds, rather than a premix incorporating all three of these compounds.

21CFR 558.76, 558.195, and 558.530

### NADANumber: 141-085

Trade Name: ZOAMIX<sup>®</sup>, BMD<sup>®</sup>  
Ingredients: Zoalene, bacitracin methylene disalicylate  
Sponsor: Alpharma, Inc.  
Approval Date: 06/03/98  
Status: Over-the-counter  
Route: Oral  
Species: Avian (turkey)  
Drug Form: Type A medicated articles to make Type C medicated feed  
Concentration: Zoalene 113.5 g/lb (25%); bacitracin methylene disalicylate 10, 25, 30, 40, 50, 60, or 75 g/lb  
Indications: For the prevention and control of coccidiosis, for increased weight gain, and improved feed efficiency in growing turkeys.  
Tolerance: 21 CFR 556.770: Zoalene (and its metabolite 3-amino-5-nitro-o-toluamide): 3 ppm in uncooked muscle tissue and liver.  
21CFR 556.70: Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of turkeys  
Withdrawal: Zero days

This NADA provides for the combined use of two approved Type A medicated articles in the manufacture of Type C medicated feeds, rather than a premix incorporating both of these compounds.

21CFR 558.76 and 558.680

### NADA Number: 141-088

Trade Name: HISTOSTAT<sup>®</sup>, BMD<sup>®</sup>  
Ingredients: Nitarsone, Bacitracin methylene disalicylate  
Sponsor: Alpharma, Inc.  
Approval Date: 06/17/98  
Status: Over-the-counter  
Route: Oral  
Species: Avian (turkey)  
Drug Form: Type A medicated articles to make Type C medicated feed  
Concentration: Nitarsone 227g/lb; bacitracin methylene disalicylate 10, 25, 30, 40, 50, 60, 75 g/lb  
Indications: As an aid in the prevention of blackhead, for increased weight gain, and improved feed efficiency in growing turkeys.  
Tolerance: 21CFR 556.70: Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of turkeys  
21CFR 556.60: Arsenic residues: 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of turkeys.  
Withdrawal: 5 days

## Actions Taken by FDA Center for Veterinary Medicine

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### **NADA Number: 141-088, con't**

This NADA provides for the combined use of two approved Type A medicated articles in the manufacture of Type C medicated feeds, rather than a premix incorporating both of these compounds.

21CFR 558.76 and 558.369

### **Supplemental Approvals**

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#### **NADA Number: 046-666**

Trade Name: Procaine G Penicillin 50% Type A Medicated Article  
Ingredients: Procaine G Penicillin  
Sponsor: Alpharma, Inc.  
Approval Date: 04/10/98  
Status: Over-the-counter  
Route: Oral  
Species: Porcine, Avian (chickens, pheasants, quail, and turkeys)  
Drug Form: Type A medicated article to make Type C medicated feeds  
Concentration: 50%  
Indications: For increased rate of weight gain and improved feed efficiency.  
Tolerance: 21CFR 556.510 (a) Zero in the uncooked edible tissues of chickens, pheasants, quail, and swine.  
(b) 0.01 ppm in the uncooked edible tissues of turkeys.  
Withdrawal: Zero days

This supplemental application provides for compliance with the conclusions of the National Academy of Science/National Research Council (NAS/NRC) evaluation of penicillin-containing Type A Medicated Articles.

21CFR 558.460

#### **NADA Number: 046-668**

Trade Name: Procaine G Penicillin 50% Type A Medicated Article  
Ingredients: Procaine G Penicillin  
Sponsor: Pfizer, Inc.  
Approval Date: 04/10/98  
Status: Over-the-counter  
Route: Oral  
Species: Porcine, Avian (chickens, pheasants, quail, and turkeys)  
Drug Form: Type A medicated articles to make Type C medicated feeds  
Concentration: 60 or 136 grams/ton  
Indications: For increased rate of weight gain and improved feed efficiency.  
Tolerance: 21CFR 556.510 (a) Zero in the uncooked edible tissues of chickens, pheasants, quail, and swine.  
(b) 0.01 ppm in the uncooked edible tissues of turkeys.  
Withdrawal: Zero days

This supplemental application provides for compliance with the conclusions of the National Academy of Science/National Research Council (NAS/NRC) evaluation of penicillin-containing Type A Medicated Articles.

21CFR 558.460

#### **NADA Number: 140-989**

Trade Name: Parasite-S  
Ingredients: Formalin  
Sponsor: Western Chemical, Inc.  
Approval Date: 06/18/98  
Status: Over-the-counter  
Route: In the environmental water

## Actions Taken by FDA Center for Veterinary Medicine

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### NADA Number: 140-989, con't

Species: Fish (all finfish including their eggs), penaeid shrimp  
Drug Form: Liquid (solution)  
Concentration: 37% w/w formaldehyde gas in water  
Indications: For the control of external protozoa (*Chilodonella* spp., *Costia* spp., *Epistylis* spp., *Ichthyophthirius* spp., *Scyphidia* spp., and *Trichodina* spp.) and the monogenea parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.) on all finfish; the control of fungi of the family Saprolegniaceae on all finfish eggs; and the control of external protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.) on penaeid shrimp.

This supplemental application provides for the expansion of indications as cited above.

21CFR 529.1030

### NADA Number: 065-470

Trade Name: BMD<sup>®</sup> Soluble  
Ingredients: Bacitracin methylene disalicylate  
Sponsor: Alpharma, Inc.  
Approval Date: 05/27/98  
Status: Over-the-counter  
Route: Oral (drinking water)  
Species: Avian (quail)  
Drug Form: Powder  
Concentration: Each 4.1 oz packet contains 51.2 g bacitracin activity from bacitracin methylene disalicylate equivalent to 200 g/lb bacitracin.  
Indications: For the prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate.  
Tolerance: 21 CFR 556.70: The tolerance for residues of bacitracin in uncooked tissues of chickens, turkeys, and quail has been established as 0.5 ppm.  
Withdrawal: Not required.

This supplemental application provides for the addition of a new species, growing quail, to be added to the previously approved product.

21CFR 520.154a

### NADA Number: 101-479

Trade Name: Banamine<sup>®</sup> Injectable Solution  
Ingredients: Flunixin meglumine  
Sponsor: Schering-Plough Animal Health Corp.  
Approval Date: 05/06/98  
Status: Prescription only  
Route: Intravenous  
Species: Bovine (beef cattle and non-lactating dairy cattle)  
Drug Form: Liquid (solution)  
Concentration: 50 mg/mL  
Indications: For the control of pyrexia associated with bovine respiratory disease and endotoxemia, and for the control of inflammation in endotoxemia.  
Tolerance: 21 CFR 556.286: Acceptable daily intake (ADI) is 0.72 micrograms/kg/day. A tolerance is established for parent flunixin free acid of 0.125 ppm in liver (target tissue) and 0.025 ppm in muscle.  
Withdrawal: 4 days  
Exclusivity: 3 years

This supplemental application provides for an additional species, cattle, to be added to the previously approved product.

21CFR 522.970 and 556.286

## Actions Taken byFDA Center for Veterinary Medicine

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### NADANumber: 046-592

Trade Name: BMD®  
Ingredients: Bacitracin methylene disalicylate  
Sponsor: Alpharma, Inc.  
Approval Date: 06/22/98  
Status: Over-the-counter  
Route: Oral  
Species: Avian (replacement chickens)  
Drug Form: Type A medicated article to make Type C medicated feeds  
Concentration: 10, 25, 30, 40, 50, 60, or 75 g/lb  
Indications: As an aid in the prevention and control of necroticenteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate.  
Tolerance: 21CFR 556.70: Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of chickens.

This supplemental application provides for the addition of a class, replacement chickens, to be added to the previously approved product.

21CFR 558.76

## Change of Sponsor

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### NADA Numbers: 091-818 & 094-170

From: Danbury Pharmacal, Inc.  
To: Phoenix Scientific, Inc.  
3915 South 48<sup>th</sup> St. Terrace  
P.O. Box 6457  
St. Joseph, MO 64506-0457  
Drug labeler code: 059130

## Suitability Petition Action

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Number: 98P-0232/CP1  
Sponsor: Virbac, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug miconazole nitrate which differs from the pioneer product, Conofite® Lotion 1%, Schering-Plough Animal Health Corporation, NADA 095-184, by the following characteristics: Miconazole 2% is formulated as a leave-on conditioner and Conofite® Lotion 1% is formulated as a topical lotion and a different strength.  
Action: Denied on 7/08/98.

Number: 98P-0580/CP1  
Sponsor: Delmarva Laboratories, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe® Capsules, Pharmacia & Upjohn Co., NADA 120-161, by the following characteristics: Clindamycin hydrochloride generic is a tablet and Antirobe® is a capsule.  
Action: Filed on 7/16/98.